

## **REMARKS**

### **Status of Claims**

By this Amendment, claims 29 and 34-35 are cancelled without waiver, prejudice or estoppel. Claims 1, 2, 11, 17, 18, 28, 30 and 36 have been amended. Support for the amendments to claims 1 and 17-18 and 28 is found, for example, at paragraph 0060 of applicants' published specification. The remaining amendments merely combine subject matter of claims, and/or change dependencies. Applicant therefore requests entry of the amendments and reconsideration in view of the remarks herein, and allowance of pending claims 1-28, 30-33 and 36.

### **Claim rejections under 35 USC §102**

Claims 1-13, 15, 16, and 28-33 were rejected under 35 USC §102(b) as allegedly anticipated by U.S. Patent 5,284,133 to Burns et al. This rejection is respectfully traversed.

Applicants claimed device and method is for a passive lockout, that is, dispensing of the drug contained within the container is not possible with lockout mode in its **normal, or inactive** state. Put another way, the claimed dispensing lockout mechanism is actually a dispensing permitting system, authorizing dispensing only when activated.

Burns et al does not anticipate independent claim 1 or 28. As amended, claims 1 and 28 are directed to an aerosol drug delivery system comprising, inter alia, an electromechanical lockout device which prevents manual actuation of a drug formulation when in an inactive state and which permits manual actuation when in an active state.

Burns et al does not disclose a lockout device or mechanism wherein the locking out is effected when the mechanism is in its **inactive state**. This positively recited feature of applicants' claims is entirely different for the mechanisms disclosed in Burns et al which require an **active state** to achieve a lockout. The inactive state lockout of applicants' claims thus advantageously prolongs the life of the dispenser power source, as the drug dispensing mode is extremely limited in duration, compared to the non-dispensing mode. Additionally, this feature provides a fail-safe mode for locking drug

dispensing in the event of loss of power for the device, which can be important to limit dispensing of narcotic drugs.

The Examiner notes that in Burns et al, a controller (24) signals the actuator mechanism (28) to lock-up and prevent actuation of the inhalation device after a requisite number of inhalations (see column 8, lines 24-26). Burns et al thus unequivocally teaches a dispenser normally operable while the lockout mechanism is in an inactive state. It is only upon supplying current to the mechanism, activating the mechanism, that lockout is achieved. This is not the mode of operation desired (for reasons given above) that applicant's claimed invention is designed to achieve.

In addition, independent claim 28 is not anticipated by Burns et al, for at least the reasons given in respect of amended claim 1 above. Claim 28 is to an aerosol drug delivery system comprising, inter alia, a control system comprising an electromechanical lockout device which prevents manual actuation of a drug formulation when in an inactive state and which permits manual actuation when in an active state, and wherein the control system controls the opening of a valve such that a valve is only opened when a dosing condition has been satisfied at which time the locking mechanism in the active state. Accordingly, Burns et al does not anticipate claim 28.

Since Burns et al does not disclose each and every feature set forth in claim 1 or 28, it does not anticipate either claim. Thus, the Examiner is respectfully requested to withdraw the rejection under 35 USC §102.

With respect to the rejection of individual elements claimed in the dependent claims, as the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of independent claims 1 and 28, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

**Claim rejections under 35 USC 103(a)**

Claims 17-27 were rejected under 35 USC §103(a) as being unpatentable over Burns et al. The rejection is traversed, for at least the reasons given in response to the rejection of claims 1-13, 15, 16, and 28-33 under 35 USC §102, above. Moreover, Burns et al actually **teaches away** from applicant's claimed dispensing system by disclosing only a system or system which requires activation to achieve the lockout. Burns thus teaches an active lockout system, instead of the passive one claimed by applicants.

As noted above, Burns et al does not teach an electromechanical lockout device that is **normally in an inactive state**, drawing no power, and preventing dispensing. Since Burns et al does not teach or suggest all claimed elements and because the Examiner has not provided reasoning as to why a modification to Burns et al that would result in a device encompassed by method of claim 17 would be obvious, the Examiner has failed to establish a prima facie case under 35 USC 103(a). Claim 17 is not properly rejectable under 35 USC §103(a) over Burns et al. Accordingly, Applicant requests withdrawal of the rejection.

Furthermore, the Examiner has relied on a single reference as the basis for rejecting applicants' claims under §103(a). When a single reference is presented to support an obviousness rejection, the Examiner must cite evidence of general knowledge in the art that, together with the reference, makes a case for obviousness, or must submit – in the form of an affidavit – Examiner's own knowledge of facts that combine with the reference to make the claimed invention obvious. See 37 CFR §1.104(d)(2); MPEP 2112(IV). The evidence must be "clear and particular." *In re Dembiczak*. Importantly, since an Examiner is, under the law, not considered one skilled in the art, the Examiner's opinion as to what one skilled in the art may (or may not) choose to do with the apparatus of Burns et al (e.g., construct a passive lockout mechanism) is of no moment. *In re Rijkkaert* ("[T]he examiner's assumptions do not constitute the disclosure of the prior art"). If the Examiner has knowledge of facts relevant to any of the pending rejections, the Examiner may file an affidavit to make those facts of record in the prosecution. The Examiner has submitted no such affidavit. The Examiner's statements do not qualify as the requisite "evidence" needed to support

an obviousness rejection. Therefore, applicant's respectfully request the rejection under 35 U.S.C. §103 be withdrawn.

Applicant requests withdrawal of the rejection of claim 17 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 18-27 which depend from claim 17 and are not rendered unpatentable by Burns et al for at least the same reasons as claim 17.

Claims 14 and 34-36 were rejected under 35 USC §103(a) as being unpatentable over Burns et al in view of U.S. Patent 4,934,358 to Nilsson et al (hereinafter Nilsson et al). The rejection is traversed.

Initially, claims 34-35 have been cancelled, rendering the rejection moot. Both claims 14 and 36 are dependent claims, depending from claim 1 (indirectly), and 28, respectively. Thus these claims are patentably distinct for at least the reasons provided in respect of the rejection of claims 1 and 28.

Moreover Nilsson et al does not teach or suggest a prevention device that prevents manual actuation when in an inactive state. Since neither Burns et al nor Nilsson et al, individually or combined, disclose, teach or suggest all positively recited features in claims 1 or 28, the rejection under 35 USC §103(a) is improper and should be withdrawn. For at least the same reason, Burns et al and Nilsson et al do not render claims 14 and 36, (which depend from claims 1 and 28, respectively), unpatentable.

Applicants thus request withdrawal of the rejection of claims 14 and 36.

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**Conclusion**

Pending claims 1-28, 30-33 and 36 are allowable for the reasons given above, and an allowance is respectfully requested.

If a telephone conference would expedite the allowance of this application, the Examiner is requested to call the undersigned at (650) 283-6790.

Respectfully submitted,  
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